DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18, 2014

SeaSpine, Incorporated
Ms. Michelle Willis
Director of Regulatory Affairs
2302 La Mirada Drive
Vista, California 92081

Re: K142488
Trade/Device Name: SeaSpine Spacer System – Hollywood™ NanoMetalene®, Pacifica™ NanoMetalene®, Redondo™ NanoMetalene®, Ventura ™ NanoMetalene®; Cambria™ NanoMetalene®; Vu aPOD-L™ NanoMetalene®; Vu ePOD™ NanoMetalene®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: September 22, 2014
Received: September 23, 2014

Dear Ms. Willis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142488

Device Name
Hollywood NanoMetalene, Pacifica NanoMetalene, Redondo NanoMetalene, Ventura NanoMetalene, Cambria NanoMetalene, Vu aPOD-L NanoMetalene, Vu ePOD NanoMetalene

Indications for Use *(Describe)*
SeaSpine Spacer System – Hollywood NanoMetalene, Pacifica NanoMetalene, Redondo NanoMetalene, Ventura NanoMetalene:

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft (autograft) and supplemental fixation.

Cambria NanoMetalene:

Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Vu aPOD-L NanoMetalene:

The Integra Vu aPOD-L Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is to be packed with autogenous bone graft (i.e. autograft). The Integra Vu aPOD-L Intervertebral Body Fusion Device is intended for use with supplemental fixation that is in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate.

Degenerative disc disease is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

Vu ePOD NanoMetalene:

When used as an intervertebral body fusion device the Vu ePOD Intervertebral Body Fusion Devices are indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft only. The Vu ePOD Intervertebral Body Fusion Devices are intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System. Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Contact Details

Applicant Name: SeaSpine, Inc. (A subsidiary of Integra LifeSciences Corporation)

Address: 2302 La Mirada Drive, Vista, CA 92081
Phone number: (760) 216-5104
Fax number: (760) 727-8891

Contact person: Michelle Willis, Director of Regulatory Affairs
Contact Phone: 760-216-5104
Email address : Michelle.Willis@integralife.com

Date Prepared: November 24, 2014

2. Device Name

Trade Name: SeaSpine Spacer System™ – Hollywood™ NanoMetalene®, Pacifica™ NanoMetalene®, Redondo™ NanoMetalene®, Ventura™ NanoMetalene®; Cambria™ NanoMetalene®; Vu aPOD-L™ NanoMetalene®; Vu ePOD™ NanoMetalene®

Common Name: Intervertebral body fusion device

Classification Name: Intervertebral fusion device with bone graft, lumbar, Product Code: MAX; Intervertebral Fusion device with bone graft, cervical, ODP

3. Legally Marketed Predicate Device(s)

Predicate	510(k) Number	Product Code	Trade Name	Manufacturer
Primary	K102026	MAX	SeaSpine Spacer System – Hollywood™ NanoMetalene®	SeaSpine, Inc.
Additional	K082310	MAX	SeaSpine Spacer – Hollywood™, Pacifica™, Redondo™, Ventura™	SeaSpine, Inc.
	K103297	MAX	SeaSpine Spacer System – Redondo™, Redondo-L™	SeaSpine, Inc.
	K082309	ODP	Cambria™	SeaSpine, Inc.
	K082712	MAX	Vu ePOD™	Theken Spine, LLC
	K112986	MAX	Vu aPOD-L™	Integra Spine

4. Device Description

The SeaSpine Spacer System (Hollywood NanoMetalene, Pacifica NanoMetalene, Redondo NanoMetalene, Ventura NanoMetalene), Cambria NanoMetalene, Vu aPOD-L NanoMetalene, Vu ePOD NanoMetalene devices are intervertebral fusion devices made from polyetheretherketone (PEEK OPTIMA LT1 per ASTM F2026) with markers (tantalum per ASTM F560 or Ti-6Al-4V ELI per ASTM F136) for radiographic visualization. The devices have a central canal for receiving autogenous bone graft and are offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy. The purpose of this 510(k) is to add a 1 micrometer surface of titanium (per ASTM F67) to the exterior surface of each of these devices.

5. Intended Use/Indications for use

The NanoMetalene subject devices have substantially equivalent indications and intended use as the cited predicates:

SeaSpine Spacer System – Hollywood NanoMetalene, Pacifica NanoMetalene, Redondo NanoMetalene, Ventura NanoMetalene:

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft (autograft) and supplemental fixation.

Cambria NanoMetalene:

Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Vu aPOD-L NanoMetalene:

The Integra Vu aPOD-L Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is to be packed with autogenous bone graft (i.e. autograft). The Integra Vu aPOD-L Intervertebral Body Fusion Device is intended for use with supplemental fixation that is

in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate.

Degenerative disc disease is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

Vu ePOD NanoMetalene:

When used as an intervertebral body fusion device the Vu ePOD Intervertebral Body Fusion Devices are indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft only. The Vu ePOD Intervertebral Body Fusion Devices are intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System. Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

6. Substantial Equivalence Comparison

The NanoMetalene subject devices are substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

7. Non-clinical Testing

Substantial equivalence was supported by engineering analysis and static and dynamic testing per ASTM F2077, wear particulate analysis per ASTM F1877, subsidence testing per ASTM F2267, as well as expulsion testing; analysis demonstrated that the titanium surface does not negatively impact mechanical performance of the NanoMetalene subject devices when compared to the predicate devices.

8. Clinical Testing

No clinical testing was required to demonstrate equivalence.

9. Conclusions

The non-clinical data demonstrate that the SeaSpine Spacer System – Hollywood NanoMetalene, Pacifica NanoMetalene, Redondo NanoMetalene, Ventura NanoMetalene, Cambria NanoMetalene, Vu aPOD-L NanoMetalene, and Vu ePOD NanoMetalene devices are substantially equivalent to the predicate devices.